KEYWORDS

THORACIC EPIDURAL

MRM IN REGIONAL

BREAST SURGERIES IN REGIONAL ANESTHESIA

BREAST SURGERIES

EPIDURAL ANESTHESIA

EPIDURAL SPACE

LEVOBUPIVACAINE IN EPIDURAL

ROPIVACAINE IN EPIDURAL

OCTOBER2017

Chennai – 10

From,

Dr. R.BRINDHA,

M.D. POST GRADUATE,

DEPT. OF ANAESTHESIOLOGY,

GOVT. KILPAUK MEDICAL COLLEGE,

CHENNAI - 10.

To,

THE DEAN,

GOVT. KILPAUK MEDICAL COLLEGE,

CHENNAI -10.

Through proper channel,

Respected Sir,

Subject:Dissertation - M.D Anaesthesiology,

Request for Ethics Committee approval regarding ,

I, Dr.R.BRINDHA, hereby submit the following necessary documents relating to my dissertation work for the approval of the Institutional Ethics committee.

"A STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY**".**

Thanking you,

Yours sincerely,

Dr. R.BRINDHA

Forwarded,

OCTOBER 2017
Chennai – 10

From,

Dr.R.BRINDHA,

M.D. POST GRADUATE,

DEPT. OF ANAESTHESIOLOGY,

GOVT. KILPAUK MEDICAL COLLEGE,

CHENNAI - 10.

To,

THE CHAIRMAN,

INSTITUTIONAL ETHICS COMMITTEE,

GOVT. KILPAUK MEDICAL COLLEGE,

CHENNAI -10.

Through proper channel,

Subject: Dissertation -MD Anaesthesiology,

Request for Ethics Committee approval regarding ,

Respected Sir,

I, Dr. R.BRINDHA, hereby submit the following necessary documents relating to my dissertation work for the approval of the Institutional Ethics committee.

"A STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY**".**

Thanking you ,

Yours sincerely,

Forwarded

Dr. R.BRINDHA

I also submit the following undertaking:

1) I will start the study only after obtaining the approval of Institutional Ethical Committee (IEC).

2) I will get the informed consent from the patient and maintain confidentiality of the details.

3) I will carry out the work without detrimental to the regular activities as well as without extra expenditure to the institution or the government.

4)I will inform the committee in the event of any change in the study procedure, site, investigations or guide.

5)I will not deviate from the area of work for which I have applied to the ethical committee.

6)I will inform the IEC in the event of any adverse events encountered in my study.

7)I will abide the rules and regulations of the institution.

8)I will complete the work within the specified period and if there is any extension of my work, I will apply for the permission again and continue the work.

9)I will submit the summary/report of my work on completion of my work to the IEC.

10)I will not claim any funds from the institution while doing or after completing the work.

11)I understand the members of IEC have the right to monitor my study without prior intimation.

Thanking you,

Yours sincerely,

Forwarded,

DR R.BRINDHA

APPLICATION FOR ETHICS COMMITTEE CLEARANCE CERTIFICATE

DECLARATION BY THE STUDENT

I,**Dr.R.BRINDHA M.D. (Anaesthesiology)Post Graduate**, hereby apply for the EthicsCommittee clearance certificate for my dissertaion topic titled,

"A STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY**".**

under the guidance ofProf.Dr.T. Murugan M.D., D.AProfessor , DeptOfAnaesthesiology, Government KilpaukMedical College andhospital, Chennai – 10.

I understand the implications of doing research with human subjects and willcomply with the regulations and protect the health & rights of the participants at all cost.

Signature of the candidate

Dr.R.BRINDHA

DECLARATION BY THE GUIDE

I Prof.Dr.T. Murugan M.D., D.Awill guide my M.D post graduate inAnaesthesiology,Dr.R.BRINDHAfor his thesis (protocols mentioned above)without compromising the ethical principles & scientific norms and the care of the patients concerned and I also assure that utmost humanitarian principles will be followedwhile conducting the study.

Signature of the Guide

Prof.Dr.T. Murugan M.D., D.A

Dept. of Anaesthesiology, KMC

I have no objection in guiding Dr.R.BRINDHA, M.D. (Anaesthesiology)postgraduate in the project mentioned above. I shall supervise that allhuman rights are protected and research is carried out with utmosthumanitarian principles.

Signature of the HOD

Prof.Dr.T. Murugan M.D., D.A

Dept. of Anaesthesiology, KMC

RECOMMENDATION OF THE GUIDE

The study titled **"A** STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY**"**by Dr.R.BRINDHA, M.D.(Anaesthesiology) Postgraduate will be done as per the recommendations of Ethics committee in the Department of Anaesthesiology. I shall supervise that all human rights are protected and research is carried out with utmost humanitarian principles.

Signature of the Guide

Prof.Dr.T. Murugan M.D., D.ADept. of Anaesthesiology, KMC

RECOMMENDATION OF THE HOD

The study titled **"A** STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY**"**byDr.R.BRINDHA M.D. (Anaesthesiology) Post Graduate will be done as per the recommendations of Ethics committee in the Department of Anaesthesiology. I shall supervise that all human rights are protected and research is carried out with utmost humanitarian principles.

Signature of the HOD

Prof.Dr.T. Murugan M.D., D.A

Dept. of Anaesthesiology, KMC

PROTOCOL

Name : Dr.R.BRINDHA

Course : MD Anaesthesiology(MAY 2016 – MAY 2019)

Duration : 6 months

Topic :**"A** STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY**".**

Guide : Prof.Dr.T. Murugan M.D., D.A

Professor of Anaesthesiology,

Department of Anaesthesiology,

Govt. Kilpauk Medical College and Hospital,

Chennai 10.

Center : Govt. Kilpauk Medical College and

Govt.RoyapettahHospital, Chennai.

Study Design: A prospective , Non –Randomized, double Arm,

Single-Blinded,controlled study..

”A STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY**”.**

INTRODUCTION:

Thoracic epidural anesthesia is increasingly being used for abdominal, major vascular and cardiothoracic & breast surgeries. The objective of thoracic block is not solely to block noxious afferent stimuli from the surgical site, but to impart a bilateral selective thoracic sympathectomy. Provision of pain relief and sympatholysis of such magnitude that allows patients to cough, breath deeply and mobilize can contribute to enhanced postoperative outcomes such as improved respiratory function, reduction in ileus , nausea and vomiting.

Levobupivacaine and ropivacaine, the two new long-acting local anesthetics, have been developed as an alternative to bupivacaine, after the evidence of its severe toxicity. Both of these agents are pure left-isomers and, due to their three-dimensional structure, seem to have less toxic effects on the central nervous system (CNS) and on the cardiovascular system

Ropivacaine is produced as pure “S” enantiomer withlower lipid solubility, easier reversibility after inadvertent intravascular injection, significant reduction in central nervous system toxicity, lesser motor block and greater differentiation of sensory and motor block. Increasing concentrations caused quicker onset, greater intensity, slower regression, and longer duration of motor blockade. It is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibers resulting in a relatively reduced motor blockade. The reduced lipophilicity is also associated with decreased potential for CNS and cardiotoxicity. Thus, ropivacaine appears to be an important option for regional anesthesia and for the management .

Levobupivacaine, the isolated S(-) enantiomer of bupivacaine, has been shown to be less cardiotoxic than bupivacaine in preclinical studies. Owing to the lower affinity of the S(-) isomer to the cardiac sodium channels compared to the R(+) isomer, it is associated with less cardiac side effects.

Both of these agents are pure left isomers, and based on their three-dimensional structure; they have less toxicity to both the central nervous system and the heart. The clinical profiles of levobupivacaine and ropivacaine are similar to that of racemic bupivacaine, and the minimal differences among the three agents are mainly related to the slightly different anesthetic potency. They produce effects similar to other local anesthetics via reversible inhibition of sodium ion influx in nerve fibers. Hence, in this study to compare the effects oflevobupivacaine 0.5% and ropivacaine 0.75% in thoracic epidural anesthesia for modified radical mastectomy.

OBJECTIVES OF THE STUDY:

The aim of the study is to compare0.5%levobupivacaine and 0.75% ropivacaine in thoracic epidural for modified radical mastectomy by assessing

1. Time of onset
2. Duration,i.e, time interval between epidural drug bolus and first epidural drug requirement.
3. Requirement of sedatives
4. Cardio toxicity i.e monitoring vital parameters, electrocardiography, blood pressure, heart rate
5. Conversion of general anesthesia
6. Patient comfort i.e.visual pain analogue scale

REVIEW OF LITERATURE:

Dr. ShalinaChandranet al.

It is important that new local anaesthetics that have lower cardiotoxicity are adopted to ensure that regionaltechniques using large amounts of local anaesthetics remain safe with minimal complications. In the
present study using 0.75% ropivacaine and 0.5% bupivacaine epidurally, there were no significant differences in the block parameters but ropivacaine was associated with relatively longer duration of postoperative analgesia.

VijetaMaheshwari et al In the present study, we selected two different dosages of local anesthetics – i.e., 0.5% levobupivacaine for comparison against 0.75% ropivacaine for comparison. The reason for this was a reported slower onset time for ropivacaine as compared to levobupivacaine for the same dose. However, an enhanced dose of ropivacaine (0.75%) has been shown to be comparable to a lower dose of levobupivacaine (0.5%).[8]

Bajwa*et al*.,[10] who showed that epidural administration of 0.75% ropivacaineepidurally shows a declining trend from around 75 min postadministration interval. HR lowering effect of epidural ropivacaine has been proven in animal studies 60 min after administration.[11] Thus, it can be seen that both the drugs have a similar effect on HR which varied under different conditions. As far as the present study is concerned, both the drugs showed a similar effect and did not differ significantly. For none of the drugs, any side effect in terms of bradycardia was noticed.

Casati and Baciarello et al [12] reported that levobupivacaine 0.5% produces an epidural block of similar onset,
quality, and duration as by the same volume of 0.5% bupivacaine with a motor block deeper than thatproduced by 0.5% ropivacaine.

MATERIALS AND METHODS

SOURCE OF DATA:

Patients undergoing modified radical mastectomy done under general anesthesiaat Govt. KilpaukMedical College and Govt. Royapettah Hospital, Chennai between February 2018 and july 2018will be assessed for inclusion and exclusion criteria and will be included in the study after obtaining written informed consent.

SAMPLE SIZE:60

Sample size was determined based on the study ”a study on comparision of 0.5%levobupivacaine and 0.75% ropivacaine in thoracic epidural for modified radical mastectomy”

Description:

The formula for determining sample size is given as:

$$n = \left(\frac{z_{\alpha/2} \cdot \sigma}{E}\right)^2$$

Where
n = Sample size
σ = Population standard deviation
e = Margin of error
Z = The value for the given confidence interval

- The confidence level is estimated at 95%
- Standard deviation 58
- With a z value of 1.96
- The confidence interval or margin of error is estimated at +/-15
- Assuming that 80 percent as power of the study, minimum sample size required for the study was calculated to be 58.

In our study 60 subjects were chosen

(n=30 in GroupA , n= 30 in Group B)

STUDY DESIGN:

A prospective,Non –Randomized, double Arm, Single-

Blind, Controlled study

INCLUSION CRITERIA:

1) Patients undergoing elective modified radical mastectomy under thoracic epidural anesthesia.
2) Age between 30 to 60 years
3) Females
4) ASA class 1 and 2
5) Patients who have given valid informed consent

EXCLUSION CRITERIA:

1) Patients not satisfying inclusion criteria.
2) Patients with an allergy or sensitivity to opioid group of drugs and local anesthetics.
3) Patients with spinal deformities
4) Any contraindication to epidural anesthesia
5) Patients with neurological disorders
6) Impaired ability to communicate (e.g., confusion, poor hearing or language barrier)
7) Patients who are unconscious or severely ill.
8) Pregnant patients.
9) Patients with Coagulation disorders.

MATERIALS:

1) Boyles apparatus
2) Laryngoscope with different blade sizes
3) Other airway gadgets used in case of difficult intubation
4) Endotracheal tubes
5) Drugs for administering general anesthesia
6) Epidural needle and catheter set
7) Glass syringe
8) Inj. Fentanyl , available as ampoules(one ampoule contains 2ml, each ml contains 50 mcg of Fentanyl)
9) Inj. Levobupivacaine available as vials in concentration of 0.5% (one ampoule contains 10 ml , each ml contains 5mg)
10) Inj. Ropivacaineavailable as vials in concentration of 0.75% (each vial contains 20 ml, each ml contains 7.5 mg)
11) Inj.midazolam1mg/ml total 5mg/5ml vial.

METHODOLOGY:

Patients in the above mentioned inclusion criteria selected will be counselled about the risks and benefits involved in the study. After getting consent, patients who are willing to be included in the study will be enrolled and analyzed. A total of 60 patients will be included in the study.Patients will be divided into two groups of 30 in each based on computerized random number into group A and group B.The patients in Group A will be receiving 0.5% levobupivacaine ,the patients in Group B will receive solution containing 0.75% ropivacaine.The total volume of drug in either group will be 15ml.

This study is designed as a prospective, comparative study. Patients will be preoperatively evaluated, clinically examined and proper investigations will be done prior to the assessment. Procedures will be explained in detail and written consent will be obtained.The procedure will be carried out in the theatre. Routine monitoring included ECG, Pulse Oximetry, NIBP. Intravenous cannulation done with 18G venflon.

Under sterile aseptic precautions, with patient in right lateral position ,midline or paramedian approach ,at the level of T3-T4 intervertebral space, after subcutaneous infiltration of 2ml of 2% lignocaine, using 18G epidural needle, epidural space is identified by loss of resistance technique, and 20 G catheter is threaded in via the needle. After ensuring that blood or cerebrospinal fluid was not aspirated via catheter, 3ml of 2% lignocaine with adrenaline(1:2,00,000) dilution was administered via it.

.The epidural drug administration is given 15 ml in both groups before 20 minutes of incision and sedation with inj.fentanyl 100mcg for both groups and for maintenance drugs given according to the duration.

ASSESSMENT CRITERIA	Group A	Group B
Onset of action		
Duration		
Visual pain analogue scale		
Heart rate		
Blood pressure		
Oxygen saturation		
Respiratory rate		
Conversion of general anesthesia		
Hypotension		
Paresthesia		

METHOD OF COLLECTION OF DATA

60 patients enrolled in the study who undergo elective modified radical mastectomy under thoracic epidural anesthesia will be assessed individually. The parameters mentioned above in the table will be recorded at every 15 minutes throughout the surgery. The epidural top up dose will be 8ml of 0.5% levoBupivacaine in group A , 8ml of 0.75% ropivacaine in group B.

Duration of analgesia is calculated from the time of epidural bolus to the time when first top up dose is required.

STATISTICAL ANALYSIS:

Descriptive statistics will be done for all data and reported in terms of mean values and percentages.Suitable statistical tests of comparison will be done.

Continuous variables will be analysed with the unpaired t test and ANOVA single factor test.

Categorical variables will be analysed with the Chi-Square Test and Fisher Exact Test.

Statistical significance will be taken as $P<0.05$. The data will be analysed using SPSS version 16 and Microsoft Excel 2007.

References:

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INFORMED CONSENT FORM

STUDY:"A STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY"

STUDY CENTRE: GOVT. KILPAUK MEDICAL COLLEGE & GOVT ROYAPETTAH HOSPITAL, CHENNAI

PATIENT'S NAME:

PATIENT'S AGE:

I.P NO :

Patient may check ( ) these boxes

I confirm that I understood the purpose of the procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected.

I understand that the ethical committeemembers and the regulatory authorities will need not my permission to look at my health records, both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law.

I agree not to restrict the use of any data or results that arise from the study.i agree to take part in the above study and to comply with the instructions given during the study and faithfully co operate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms.

I hereby consent to participate in this study.

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests.

Signature / thumb impression:

Patient's name and address: place:
date:

Signature of the investigator:

Study investigator's name: place:
date:

PARTICIPANTS" INFORMATION SHEET

Investigator : - Dr.R.BRINDHA

Name of the participant : -

Title**"A** STUDY ON COMPARISION OF 0.5%LEVOBUPIVACAINE AND 0.75% ROPIVACAINE IN THORACIC EPIDURAL FOR MODIFIED RADICAL MASTECTOMY**"**

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria.

What is the purpose of this research?

In this study, efficacy of0.5% levobupivacaine and 0.75 % of ropivacaine compared in thoracic epidural.so we can use this new drug as a sole epidural and also to asses the benefits and complications.In future both drugs will be used extensively because of less complications and prolonged duration of action…

BENEFITS:

This study will help us in determining efficacy ,duration ,pospoperative analgesia, requirement of sedatives during thoracic epidural and also to asses the cardiotoxicity and neurotoxicity…It also helps in reducing the requirements of other opioidanalgesic drugs and NSAIDS given via systemic route in the postoperative period which causes many side effects like nausea, vomiting, itching, respiratory depression.

DISCOMFORTS AND RISKS:

Thoracic epiudural for modified radical mastectomy may cause discomfort or anxiety during surgeries. Sometimes intercostal paralysis causes respiratory depression.Local anesthesia toxicity may also occur..

CONFIDENTIALITY:

Patients who participated in the study and their details will

be maintained confidentially and at any cost, those details will not be let out

RIGHT TO WITHDRAW :

Patients will not be forced to complete the study. At any cost, in such circumstances the treatment will not be compromised.

Date : Signature of the investigator:

Place:

Signature/Thumb impressionof the participant

<u>சுயஒப்புதல்படிவம்</u>

<u>ஆய்வுசெய்யப்படும்தலைப்பு</u>

கீழ்ப்பாக்கம்அரசுமருத்துவமனைமற்றும்ராயபேட்டை அரசுமருத்துவமனையில்வயிறு அறுவைசிகிச்சைக்கு பின் முதுகுத்தண்டுவடமேல்சவ்வில் பொருத்தப்பட்டிருக்கும்வடிகுழாய்வழியாகசெலுத்தப்படும்புபிவகைன்சேர்க்கப்பட்டபுபிவகைன், ரொப்பிவாகன்ஆகியவற்றின்வலிநிவாரணிபண்புகளைஒப்பிட்டுஆய்வு.

<u>ஆராய்ச்சிநிலையம்</u>:

மயக்கவியல்மருத்துவத்துறை,கீழ்ப்பாக்கம்மற்றும்ராயபேட்டைமருத்துவக்கல்லூரிஅரசுமருத்துவமனை, சென்னை

பங்குபெறுபவரின்பெயர்: **உறவுமுறை:**

பங்குபெறுபவரின்எண்:

பங்குபெறுபவர்இதனை (√) குறிக்கவும்

மேலேகுறிப்பிட்டுள்ளமருத்துவஆய்வின்விவரங்கள்எனக்குவிளக்கப்பட்டது.
என்னுடையசந்தேகங்களைக்கேட்கவும்,

அதற்கானதகுந்தவிளக்கங்களைப்பெறவும்வாய்ப்பளிக்கப்பட்டது.

நான்இவ்வாய்வில்தன்னிச்சையாகத்தான்பங்கேற்கிறேன்.
எந்தக்காரணத்தினாலோஎந்தக்கட்டத்திலும்எந்தசட்டசிக்கலுக்கும்உட்படாமல்நான்இவ்வாய்வில்இருந்துவிலகிக்கொள்ளலாம்என்றும்அறிந்துகொண்டேன்.

இந்தஆய்வுசம்மந்தமாகவும்,
மேலும்இதுசார்ந்தஆய்வுமேற்கொள்ளும்போதும்,
இந்தஆய்வில்பங்குபெறும்மருத்துவர்என்னுடையமருத்துவஅறிக்கைகளைப்பார்ப்பதற்குஎன்அனுமதிதேவையில்லைஎனஅறிந்துகொள்கிறேன்.
நான்ஆய்வில்இருந்துவிலகிக்கொண்டாலும்இதுபொருந்தும்எனஅறிகிறேன்.

இந்தஆய்வின்மூலம்கிடைக்கும்தகவல்களையும்,
பரிசோதனைமுடிவுகளையும்மற்றும்சிகிச்சைதொடர்பானதகவல்களையும்மருத்துவர்மேற்கொள்ளும்ஆய்வில்பயன்படுத்திக்கொள்ளவும்,
அதைப்பிரசுரிக்கவும்என்முழுமனதுடன்சம்மதிக்கிறேன்.

இந்தஆய்வில்பங்குகொள்ளஒப்புக்கொள்கிறேன்.
எனக்குக்கொடுக்கப்பட்டஅறிவுரைகளின்படிநடந்துகொள்வதுடன்,
இந்தஆய்வைமேற்கொள்ளும்மருத்துவஅணிக்குஉண்மையுடன்இருப்பேன்என்றும்உறுதியளிக்கிறேன்.
என்உடல்நலம்பாதிக்கப்பட்டாலோஅல்லதுஎதிர்பாராத

வழக்கத்திற்குமாறாகநோய்க்குறிதென்பட்டாலோஉட
னேஅதைமருத்துவஅணியிடம்தெரிவிப்பேன்எனஉறுதி
அளிக்கிறேன்.

இந்தஆய்வில்எனக்குமருத்துவப்பரிசோதனை,வயி
று அறுவைசிகிச்சைக்கு பின்
முதுகுத்தண்டுவடமேல்சவ்வில்
பொருத்தப்பட்டிருக்கும்வடிகுழாய்வழியாகசெலுத்தப்ப
டும்புபிவகைன்,ரொப்பிவாகன்ஆகியவற்றின்வலிநிவார
ணிபண்புகளின்ஒப்பிட்டுஆய்வுகுறித்துஆராய்ச்சிசெய்
துகொள்ளநான்முழுமனதுடன்சம்மதிக்கிறேன்.

பங்கேற்பவரின்கையொப்பம்
.....

இடம் .....தேதி .....

கட்டைவிரல்ரேகை:

பங்கேற்பவரின்பெயர்மற்றும்விலாசம்
.....
.....

ஆய்வாளரின்கையொப்பம்
.....

இடம் ..... தேதி .....

ஆய்வாளரின்பெயர்
.....

பங்கேற்பாளர் தகவல்தாள்

கீழ்ப்பாக்கம்அரசுமருத்துவமனைமற்றும்ராயபேட்டை அரசுமருத்துவமனையில்வயிறு அறுவைசிகிச்சைக்கு பின் முதுகுத்தண்டுவடமேல்சவ்வில் பொருத்தப்பட்டிருக்கும்வடிகுழாய்வழியாகசெலுத்தப்படும்புபிவகைன், ரொப்பிவாகன் வலிநிவாரணிபண்புகளின்ஒப்பிட்டுஆய்வு செய்யஉள்ளோம்.

நீங்கள்இந்தஆராய்ச்சியில்பங்கேற்கநாங்கள்விரும்புகிறோம்.
இந்தஆராய்ச்சியில்பங்கேற்பதால்தங்களதுநோயின்ஆய்வறிக்கையோஅல்லதுசிகிச்சையோபாதிக்கப்படாதுஎன்பதையும்தெரிவித்துக்கொள்கிறோம்.

இந்தஆராய்ச்சியின்முடிவுகளைஅல்லதுகருத்துகளைவெளியிடும்போதோஅல்லதுஆராய்ச்சியின்போதோ தங்களதுபெயரையோஅல்லதுஅடையாளங்களையோ வெளியிடமாட்டோம்என்பதையும்தெரிவித்துக்கொள்கிறோம்.

இந்தஆராய்ச்சியில்பங்கேற்பதுதங்களுடையவிருப்பத்தின்பேரில்தான்இருக்கிறது.

மேலும்நீங்கள்எந்நேரமும்இந்தஆராய்ச்சியில்இருந்துபி
ன்வாங்கலாம்என்பதையும்தெரிவித்துக்கொள்கிறோம்.

இந்தசிறப்புப்பரிசோதனைகளின்முடிவுகளைஆரா
ய்ச்சியின்போதோஅல்லதுஆராய்ச்சியின்முடிவின்போ
தோதங்களுக்குஅறிவிப்போம்என்பதையும்தெரிவித்துக்
கோள்கிறோம்.

ஆராய்ச்சியாளர்

பங்கேற்பாளர்கையொப்பம்

கையொப்பம்

தேதி: